



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,530	09/22/2003	Peter Fromherz	2923-566	5890
6449	7590	11/07/2005	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C.			MARTIN, PAUL C	
1425 K STREET, N.W.			ART UNIT	
SUITE 800			PAPER NUMBER	
WASHINGTON, DC 20005			1655	

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,530

Applicant(s)

FROMHERZ ET AL.

Examiner

Paul C. Martin

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>02/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-22 are pending in this application.

Election/Restrictions

Applicant's election with traverse of Group I (Claims 1-13) in the reply filed on 10/03/05 is acknowledged. The traversal is on the ground(s) that the inventions of Groups I and II are capable of use together. This is not found persuasive because of the reasons discussed in the previous restriction. Further, the device of Group II and the method of Group I would be related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process for determining whether a substance is a modulator of a target component in a cell could be performed by hand.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Art Unit: 1655

Applicant's election of the species, wherein "potassium channels" is elected as the species Kv1.3 and "receptors" is elected as the species NMDA, is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 14-22 are hereby withdrawn from examination on the merits as they are directed toward non-elected inventions.

Claims 1-13 were examined on their merits.

Drawings

The informal drawing Figures 4A and 4B are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Art Unit: 1655

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

Claim Objections

Claim 1 is objected to because of the following informalities: in mmol/l, the "l" in Liter should be a capital "L". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrasing of 1(a) is deemed somewhat ambiguous as to whether it is the cell or the target component which is immobilized on the electrode. In light of the specification it is suggested that; "wherein said cell containing the target component is immobilized..." be substituted for clarity.

Art Unit: 1655

Regarding claim 11, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1655

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,602,399 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 1-12 are made obvious by claims 1-28 of U.S. Patent No. 6,602,399 B1.

Fromherz *et al.* teaches a method for determining if a substance modulates a receptor component of a membrane-associated voltage-controlled, ligand controlled, or mechanically controlled ion-channel/receptor system by contacting the cell with the substance, measuring a signal at an electrode, and determining the effect of the substance on the measurement signal.

Fromherz *et al.* further teaches the potassium ion channel hSlo and the ionotropic glutamate receptor NMDA, the stimulation of the target component by voltage, that the cell is in contact with *at least* one electrode, and that the potential sensitive electrode is arranged on a chip.

However, the claims 1-22 of U.S. Patent No. 6,602,399 B1 do not specifically teach one of the particulars of instant claims 1-12, i.e. wherein the medium has a salt concentration of $\leq 100\text{mmol/L}$, the ordinary artisan would have been motivated to experiment with different concentrations of salt solutions in order to optimize the experimental procedure. Further, it is noted that in claim 10 the application of AC or DC voltage is specified. While claims 1-22 of U.S. Patent No. 6,602,399 B1 do not specifically teach what form of voltage is applied it is understood by the ordinary artisan that one of these forms of electric current would have been used.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being obvious over Fromherz *et al.* (WO/2001/07002).

Fromherz *et al.* teaches a method for determining whether a substance is a modulator of a membrane-associated voltage-controlled, ligand controlled, or mechanically controlled ion-channel/receptor system. (Pg. 3, Lines 47-50, Pg. 2, Lines 9-12)

Fromherz *et al.* teaches that the ion channel is a potassium channel hSlo (Pg. 2, Lines 47-48), that the ion-channel receptor system contains NMDA receptor (Pg. 3, Lines 1-2), that stimulation of the target component can be carried out via electrical, optical, or chemical means (Pg. 3, Lines 4-11), as mentioned above an inherent characteristic of voltage is that it is in either AC or DC form.

Fromherz *et al.* teaches that the cell is in contact with an additional electrode, specifically a patch clamp (Pg. 5, Lines 20-22), that the potential sensitive electrode can be arranged on a chip, (Pg. 3, Line 16) and that a multiplicity of cells can be immobilized on a chip having a multiplicity of electrodes. (Pg. 5, Lines 18-19)

Fromherz does not teach the use of a medium which has a salt concentration of ≤ 100 mmol/L or the use of an array comprising a multiplicity of cells immobilized on different electrodes for the purpose of testing a multiplicity of substances.

It would have been obvious to one skilled in the art at the time of invention to use a lower salt concentration medium because it is common laboratory practice to adjust the experimental components so as to optimize the experimental results. The ordinary artisan would have been motivated to use a lower salt concentration because of the potential for better clarity and success in obtaining results in the experiment, and would have had a reasonable expectation of success based on previous success at other concentrations.

Art Unit: 1655

It would have been obvious to one skilled in the art at the time of invention to use an array comprising a multiplicity of cells immobilized on different electrodes for the purpose of testing a multiplicity of substances because it would have been more efficient to test multiple substances at once than a series of single substances. The ordinary artisan would have been motivated to use the multiple array because of the potential for saving time and effort, and would have had a reasonable expectation of success based on the previous success testing single substances.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being obvious over
Fromherz *et al.* (U.S. 6,602,399 B1).

Art Unit: 1655

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c).

This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a).

See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Art Unit: 1655

Fromherz *et al.* teaches a method for determining if a test substance activates or inhibits a membrane associated receptor component of an ion channel/receptor system (Column 8, Claims 14 and 15), by preparing a cell containing the target component, immobilized on an extracellular potential-sensitive electrode, contacting the cell with the substance, measuring the signal at the electrode and determining the effect of the substance to be tested on the measurement signal. (Column 5, Lines 16-38)

Fromherz *et al.* teaches that the ion-channel/receptor system contains a voltage-controlled, ligand controlled or mechanically controlled ion channel (Column 2, Lines 36-42), wherein the ion channel is a potassium channel hSlo (Column 6, Line 30), the ion-channel receptor system contains an NMDA receptor (Column 3, Line 53), the target component is stimulated by electrical stimulation (Column 4, Lines 14-15), that the cell can be in contact with an additional electrode such as a patch clamp (Column 6, Lines 50-53), that the potential-sensitive extracellular electrode can be arranged on a chip (Column 8, Claim 17), and that an array comprising a multiplicity of cells immobilized on different electrodes can be prepared. (Column 6, Lines 44-45).

It would have been obvious to one skilled in the art at the time of invention to use a lower salt concentration medium because it is common laboratory practice to adjust the experimental components so as to optimize the experimental results.

The ordinary artisan would have been motivated to use a lower salt concentration because of the potential for better clarity and success in obtaining results in the experiment, and would have had a reasonable expectation of success based on previous success at other concentrations.

It would have been obvious to one skilled in the art at the time of invention to use an array comprising a multiplicity of cells immobilized on different electrodes for the purpose of testing a multiplicity of substances because it would have been more efficient to test multiple substances at once than a series of single substances. The ordinary artisan would have been motivated to use the multiple array because of the potential for saving time and effort, and would have had a reasonable expectation of success based on the previous success testing single substances.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fromherz *et al.* (WO/2001/07002) in view of Weaver (US 2002/0168625 A1).

The teachings of Fromherz *et al.* were discussed *supra* under the 103(a) rejection.

Fromherz *et al.* does not teach the use of a medium which has a salt concentration of ≤ 100 mmol/L, or that an array comprising a multiplicity of cells immobilized on different electrodes is used to test a multiplicity of substances.

Art Unit: 1655

Weaver teaches a method for identifying a modulator of an ion channel, channel-linked receptor or ion transporter using a low salt solution of 2 mmol/L Cl^- and a no salt solution (Pg. 14, Claims 13 and 15)

It would have been obvious to the person with ordinary skill at the time of the instant invention to use a salt concentration of less than or equal to 100 mmol/L, and the ordinary artisan would have been motivated to do so because the low concentration of ubiquitous salts in the surrounding solution would be less likely to interfere with the electrical signals being recorded during baseline readings or experimentation and that optimization of the salt solutions to achieve the results and conditions is a standard part of experimental procedure.

The ordinary artisan would have had a reasonable expectation of success because the solutions used by Weaver were said to "produce more robust and consistent results" than assays using known physiological salt solutions.

It is noted *supra* that Fromherz *et al.* teach the method of cultivating a multiplicity of cells immobilized on multiple electrodes. It would have been obvious to the ordinary artisan at the time of the invention that if the technique were suitable for the testing of a single substance that it would take only a little further modification to practice the technique using multiple substances.

Art Unit: 1655

The ordinary artisan would have been motivated to do so because a method of screening multiple substances would be more efficient and cost effective than simply screening one at a time, and the ordinary artisan would have had a reasonable expectation of success based on the previous success of the technique on testing a single substance.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

Art Unit: 1655

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

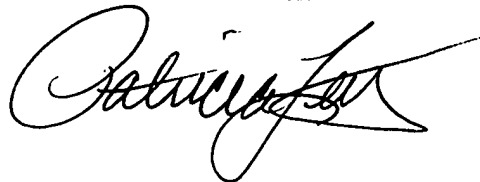
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

10/28/05

PATRICIA LEITH
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Patricia Leith', written over the printed name and title.